Homeopathic arnica for prevention of pain and bruising: randomized placebo-controlled trial in hand surgery

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SUMMARY

Homeopathic arnica is widely believed to control bruising, reduce swelling and promote recovery after local trauma; many patients therefore take it perioperatively. To determine whether this treatment has any effect, we conducted a double-blind, placebo-controlled, randomized trial with three parallel arms. 64 adults undergoing elective surgery for carpal tunnel syndrome were randomized to take three tablets daily of homeopathic arnica 30C or 6C or placebo for seven days before surgery and fourteen days after surgery. Primary outcome measures were pain (short form McGill Pain Questionnaire) and bruising (colour separation analysis) at four days after surgery. Secondary outcome measures were swelling (wrist circumference) and use of analgesic medication (patient diary).

62 patients could be included in the intention-to-treat analysis. There were no group differences on the primary outcome measures of pain (*P*=0.79) and bruising (*P*=0.45) at day four. Swelling and use of analgesic medication also did not differ between arnica and placebo groups. Adverse events were reported by 2 patients in the arnica 6C group, 3 in the placebo group and 4 in the arnica 30C group.

The results of this trial do not suggest that homeopathic arnica has an advantage over placebo in reducing postoperative pain, bruising and swelling in patients undergoing elective hand surgery.

INTRODUCTION

Homeopathy is based on the law of similars ('like cures like') which states that a substance that causes specific symptoms in a healthy person can be used to treat those symptoms in a sick person. Remedies undergo a process called 'potentization' which describes stepwise dilution from the 'mother tincture' combined with 'succession' (vigorous shaking). The underlying assumption is that the more dilute a remedy the greater its potency, even though according to Avogadro's number, with potencies beyond 12C (12 centesimal dilutions) the chance of a single molecule remaining in the final solution tends to the infinitesimal.

The alpine plant *Arnica montana* is recommended by homeopathic practitioners for treating injuries on account of its alleged ability to control bruising, reduce swelling and promote recovery[1]. Homeopathic arnica is popular with patients undergoing surgery, who hope it will reduce postoperative complications. However, despite favourable anecdotal reports[2] there is little scientific evidence of its efficacy[3]. A reduction in the pain associated with routine dental extractions has been reported in placebo-controlled trials of homeopathic arnica[4–6], but two double-blind randomized trials demonstrated no effect on pain, swelling or bleeding after surgical removal of impacted wisdom teeth[7,8]. Other trials have shown no beneficial effects on postoperative haematomas[9] or on recovery from hysterectomy[10], acute stroke illness[11,12] or childbirth[13]. Tentatively positive results were reported from a small study in patients with acute trauma[14]. A recent trial of homeopathic arnica administered in conjunction with herbal arnica ointment was reported to show no effect on swelling or grip strength but a reduction in pain following carpal tunnel release surgery[15].

As well as producing inconsistent results, many of these trials have methodological limitations that make the findings unreliable. A rigorous trial on the subject would therefore be valuable in determining whether homeopathic arnica can aid recovery from surgery. This study was designed as a preliminary investigation of the effect of this preparation on sequelae of hand surgery. If a beneficial effect of arnica (or a positive trend) was demonstrated, a larger trial would then be started.

METHODS

All patients between the ages of 18 and 70 years undergoing elective hand surgery for carpal tunnel syndrome by one

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surgeon (VSD) at the Royal Devon & Exeter Hospital or a private plastic surgery clinic were eligible for the trial. Patients were excluded if they were currently taking homeopathic remedies, reported previous hypersensitivity to homeopathy, were taking aspirin, or were unable to complete the study diary or attend follow-up appointments. Patients were not included in the trial a second time if they subsequently underwent surgery on their other hand. Patients listed for elective surgery for carpal tunnel syndrome were sent information and were invited to meet the investigators to discuss the study; each patient's general practitioner was also informed. Patients who wished to participate and who met the study criteria were allocated the next available study number.

Patients received a medication bottle, identifiable only by study number, containing either high (30C) or low (6C) potency homeopathic arnica tablets or indistinguishable placebo. Tablets were to be taken three times daily for seven days preoperatively and fourteen days postoperatively. Patients were advised to refrain from handling the tablets or from eating, drinking, smoking or brushing teeth within 20 minutes of taking the tablets and were asked to suck the tablets rather than simply swallow them. Homeopathic and placebo tablets were supplied by A Nelson & Co Ltd. Medication bottles were labelled with study numbers derived from a computer-generated randomization list in blocks of three by an individual not involved with running the trial. The randomization list was kept in a sealed envelope in a locked drawer until the end of the trial. All patients and investigators, including the surgeon, physiotherapists and data analysts, remained blind to treatment allocation until after data analysis.

All patients were admitted as day cases and received conventional preoperative and postoperative care. The operations were done under local anaesthesia. Afterwards the hand was rested on a palmar plaster splint to maintain the wrist in slight dorsiflexion, allowing the fingers to be gently mobilized within the dressing and the hand elevated in a high sling. Oral analgesic medication, either paracetamol or diclofenac, was routinely prescribed on the hospital discharge form. All patients were seen by the physiotherapist at four, nine and fourteen days post-surgery (or the closest possible day). At day four the splint was removed and digits and wrists were mobilized. A Futura aluminium wrist splint was given to the patients to wear for a further week. Sutures were removed at day fourteen.

The primary outcome measures were pain and bruising, and the secondary measures were swelling and use of analgesic medication. Pain was assessed with the short-form McGill Pain Questionnaire (SF-MPQ)[16] completed by the patient at recruitment (to provide a measure of pain from carpal tunnel syndrome) and on days four, nine and fourteen post-surgery. The SF-MPQ includes a visual analogue scale (VAS)[17] to indicate the intensity of pain and a list of fifteen descriptive words (e.g. stabbing, gnawing, shooting). The VAS is sensitive to changes in pain intensity[18]. The pain descriptors are each rated on a 4-point scale (0=none, 1=mild, 2=moderate, 3=severe) yielding a total score ranging from 0 to 45. Patients kept a daily pain diary throughout the trial, including VAS scores; they also recorded use of analgesics and any adverse events. To quantify bruising, a photograph of the patient's wrist at the distal crease was taken by the physiotherapist on days four, nine and fourteen post-surgery under standard lighting conditions. Scanned images were analysed with Adobe Photoshop 4.0 software. For each patient, frames representative of normal skin (thenar zone) and of the bruised areas (operative site) were selected. The distribution of red and blue pixels within each frame was calculated. This information, displayed as a histogram of the number of pixels (y-axis) against an increasing scale of colour brightness from 0 to 255 (x-axis), enabled an objective and quantitative comparison of the colour of the bruised area with the colour of the normal skin. This method was developed for objective measurement of burn scar hypertrophy[19] and has been successfully used to assess healing at skin graft donor sites[20]. For each patient the extent of bruising was also assessed independently by two plastic surgeons blind to treatment allocation on a 3-point scale (0=none, 1=mild–moderate, 2=severe) as a check on the validity of colour separation analysis in assessing bruising.

To quantify swelling, wrist circumference was measured at the distal wrist crease before anaesthetic infiltration and on days four, nine and fourteen post-surgery. Three readings were taken of each measurement. Adherence to the study medication was assessed by tablet counts at the end of the study. Patients were asked to tick boxes in the study diary as a further record of tablet taking. The success of patient blinding was assessed by a question in the study diary on the last day of the trial, asking patients to indicate which treatment they believed they had received (arnica, placebo, don't know).

Data analysis

The null hypothesis was that there would be no differences between the arnica and placebo groups on the primary outcome measures at day four. A search of the published work yielded no reliable data from carpal tunnel surgery on which to base a formal sample size calculation[21]. In previous studies of arnica, statistically significant effects on pain have been reported with groups of 11–30 patients[4,6,14,15]. Because of the preliminary nature of the trial and the number of patients expected to be available, a minimum sample size of 60 was considered feasible.

Since the data were not normally distributed, it was necessary to employ non-parametric statistical tests. The Kruskal–Wallis test (two-sided with 5% significance level) was used to compare the three groups at days four, nine and fourteen for pain (absolute scores), bruising (difference in colour values between normal and bruised areas), and swelling (change from pre-surgery values) and at day four only for use of analgesic medication (total number of tablets taken since surgery). Intention-to-treat analyses were conducted on all randomized patients remaining in the trial at the time of surgery. Missing data were replaced with the median value of the total sample. Analyses were performed in SPSS version 9.0 for Windows.

Ethical approval

The study protocol was approved by the Exeter Research Ethics Committee. Approval was also obtained from the Royal Devon and Exeter Healthcare NHS Trust. All participants gave written informed consent.

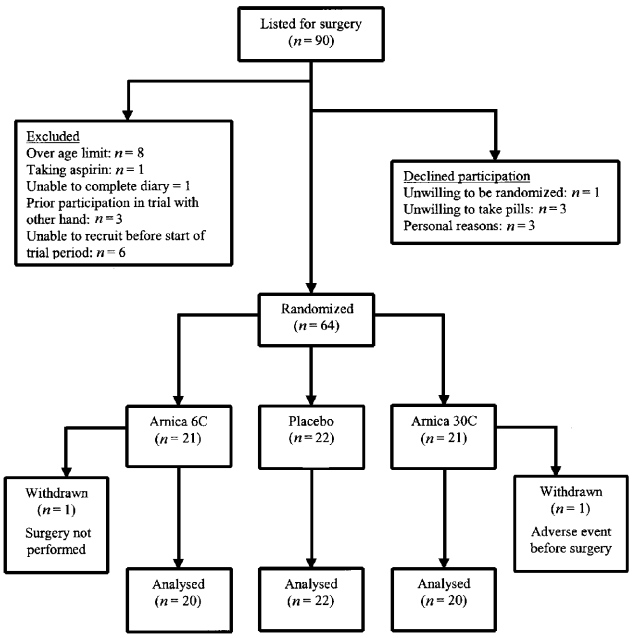

Figure 1 **Trial flow**

RESULTS

The flow of patients through the trial is displayed in Figure 1. Of the 64 patients recruited to the trial, 62 were included in the analysis. One patient in the arnica 6C group did not undergo the scheduled surgery so was no longer eligible for the trial and one patient from the arnica 30C group withdrew from the study before undergoing surgery because she believed that the tablets were causing her to feel 'unhappy or low'. 8 other patients reported adverse events—3 in the placebo group (heartburn; sore throat and flu-like symptoms; faintness and headache); 3 in the arnica 30C group (dry mouth; headache; feeling 'throbby' in head/neck); 2 in the arnica 6C group (drowsiness; sore tongue). Adherence was incomplete in all three groups. As judged by tablet counts at the end of the trial, the number of patients who had taken less than 90% of their tablets was 9/20 for the arnica 6C group, 7/22 for the placebo group and 6/20 for the arnica 30C group. Self-reported adherence was much higher, with only 2 patients indicating that they had taken less than 90% of the tablets. In total there were data missing at one or more timepoints on at least one outcome for 10 patients—3 of these were from the arnica 6C group, 5 from the placebo group and 2 from the arnica 30C group. Patient blinding seemed to remain intact throughout the study. 7/20 patients in the arnica 6C group, 3/22 in the placebo group and 7/20 in the arnica 30C group correctly identified their treatment allocation at the end of the trial. The randomization procedure resulted in similar patient characteristics in each group for most variables (Table 1). However, the arnica 6C group

Table 1 **Patient characteristics**

	***Arnica 6C* (n=20)**	***Placebo* (n=22)**	***Arnica 30C* (n=20)**
M/F	8/12	2/20	3/17
Age [years]	51.0 (30–68)	51.0 (33–57)	47.5 (30–68)
Left/right wrist	8/12	6/16	6/14
NHS/private	19/1	21/1	19/1
Wrist circumference [mm]	162.0 (140–202)	160.0 (140–190)*	163.0 (144–190)
Carpal tunnel syndrome pain			
SF-MPQ VAS [0–100]	3.0 (0–71)	20.0 (0–69)*	27.5 (0–68)
SF-MPQ descriptors [0–45]	2.0 (0–18)†	3.5 (0–24)*	6.5 (0–19)

Values are median (range) unless specified
*data missing from one patient (*n*=21)
†data missing from one patient (*n*=19)
SF-MPQ=short form McGill Pain Questionnaire; VAS=visual analogue scale; C=centesimal dilution

Table 2 **Postoperative pain**

	Arnica 6C (n=20)	*Placebo (n=22)*	*Arnica 30C (n=20)*
MPQ-SF VAS score [0–100]			
Day 4	10.5 (0–76)	16.0 (0–69)	15.0 (0–82)
Day 9	6.0 (0–31)	3.5 (0–35)	8.0 (0–49)
Day 14	0.0 (0–28)	2.0 (0–41)	8.5 (0–45)
MPQ-SF descriptors [0–45]			
Day 4	2.0 (1–16)	3.0 (0–10)	5.0 (0–24)
Day 9	2.0 (0–8)	1.0 (0–10)	3.0 (0–20)
Day 14	0.5 (0–7)	1.0 (0–6)	3.0 (0–13)

All values are median (range)
See Table 1 for key to abbreviations

Table 3 **Postoperative bruising**

	Arnica 6C (n=20)	*Placebo (n=22)*	*Arnica 30C (n=20)*
Change in blue channel brightness [0–255]*			
Day 4	26.0 (−40–59)	28.5 (−1–75)	22.0 (−14–92)
Day 9	15.5 (−33–61)	15.5 (−18–62)	11.25 (−30–81)
Day 14	11.5 (−21–69)	12.0 (−21–61)	12.5 (−32–49)
Change in red channel brightness [0–255]*			
Day 4	12.5 (−12–39)	12.5 (2–57)	20.0 (−8–60)
Day 9	13.0 (−17–69)	13.0 (−7–50)	13.5 (−22–52)
Day 14	14.5 (−17–50)	18.0 (−7–55)	17.5 (−16–42)
Clinician rating (none; mild–moderate; severe) [*n*]†			
Day 4	5;12;3	3;13;6	5;12;3
Day 9	3;14;3	4;13;5	5;14;1
Day 14	4;16;0	6;15;1	6;13;1

*Values are median (range) change from normal skin
†Ratings from two clinicians with highest value used if discrepant
C=centesimal dilution

contained more male patients and had lower VAS scores for carpal tunnel syndrome pain than the other two groups.

Results of the primary outcome measures of pain and bruising are presented in Tables 2 and 3. Postoperative pain did not differ between the groups at day 4 according to VAS scores (χ^2=4.81, d.f.=2, P=0.79) or MPQ descriptor scores (χ^2=2.48, d.f.=2, P=0.29). Similarly, bruising did not differ between the groups at day 4 in terms of blue (χ^2=1.61, d.f.=2, P=0.45) or red (χ^2=3.89, d.f.=2, P=0.14) channel brightness. The null hypothesis was therefore accepted.

There was support from the results of the secondary outcome measures of swelling and use of analgesic medication, which are presented in Tables 4 and 5 and Figure 2. Neither swelling (χ^2=1.25, d.f.=2, P=0.54) nor number of tablets (χ^2=1.63, d.f.=2, P=0.44) differed between the groups at day four. The only group difference that approached statistical significance was on the MPQ descriptors total score (χ^2=6.72, d.f.=2, P=0.04) where the placebo group had lower scores than the arnica 30C group at day nine (U=122.0, P=0.01, Mann–Whitney U test). Figure 3 displays the daily pain VAS scores from the study diary.

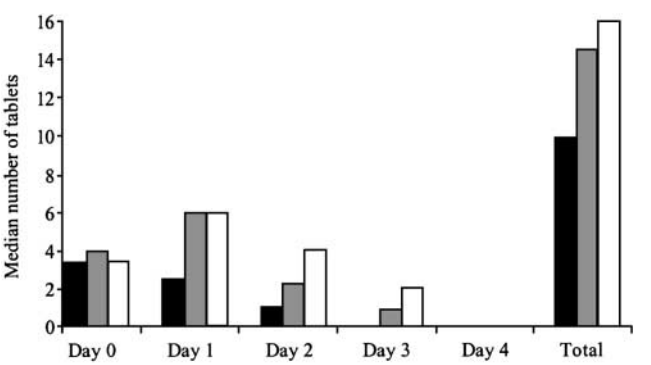

Figure 2 **Postoperative use of analgesic medication.** ■ Arnica 6C; ▒ placebo; □ arnica 30C

Table 4 **Postoperative swelling**

	Arnica 6C (n=20)	*Placebo (n=22)*	*Arnica 30C (n=20)*
Change in wrist circumference [mm]			
Day 4	6.0 (−2–12)	4.0 (−4–14)	5.0 (−2–14)
Day 9	4.0 (−4–12)	4.0 (−6–16)	6.0 (0–11)
Day 14	4.0 (−6–8)	4.0 (−4–14)	5.0 (−2–10)

All values are median (range) change from preoperative measurement
C=centesimal dilution

Table 5 **Postoperative use of analgesic medication**

	Arnica 6C (n=20)	*Placebo (n=22)*	*Arnica 30C (n=20)*
Day 0 (surgery)	3.5 (2–8)	4.0 (2–10)	3.5 (0–10)
Day 1	2.5 (0–12)	6.0 (0–18)	6.0 (0–14)
Day 2	1.1 (0–10)	1.5 (0–10)	4.0 (0–12)
Day 3	0.0 (0–8)	0.0 (0–6)	2.0 (0–12)
Day 4	0.0 (0–10)	0.0 (0–6)	0.0 (0–8)
Total	10.0 (2–46)	14.5 (2–44)	16.0 (2–50)

All values are median (range) number of tablets
C=centesimal dilution

DISCUSSION

Despite its reputation as a useful intervention for preventing the effects of anticipated trauma (e.g. surgery) or for treating unexpected trauma (e.g. accidental injury), homeopathic arnica was no better than placebo in reducing postoperative complications. These results are compatible with the negative findings from other studies[7–10,11–13,15].

This trial was designed to be a methodologically rigorous investigation of the specific effects of two potencies of homeopathic arnica. Attempts were made to select outcome measures that were objective and/or adequately validated. In particular, by employing colour separation analysis it was intended to assess bruising in a more objective quantitative manner than previous studies that have relied only on crude and subjective ratings[9,22].

These results do not support the routine use of homeopathic arnica for preventing or reducing post-operative complications such as bruising, swelling and pain. However, they do not rule out the possibility that individual patients could benefit. Homeopathic practitioners identify specific patient characteristics (e.g. fear of being touched, denial of illness, difficulty sleeping due to a hard bed, anxious dreams[2]) that help predict who will respond to arnica. This trial did not apply traditional homeopathic principles in this way. However, in one trial of surgical patients where the homeopathic remedy was chosen to match the patient's constitution, arnica was selected in 21 of 24 cases and no differences from placebo were demonstrated[8].

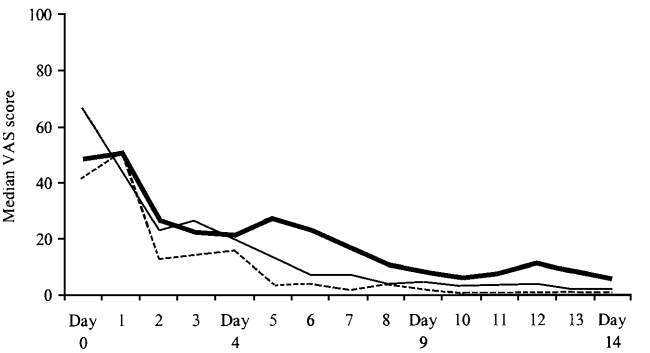

Figure 3 **Postoperative pain.** Arnica 6C; placebo; arnica 30C

The use of non-parametric tests reduces the likelihood of detecting statistical differences since they are less powerful than parametric tests particularly with smaller samples. However, a type II error does not appear to account for the results of this trial, where differences between groups are so small that they would have no clinical relevance even if statistically significant. Furthermore, there is no clear trend or consistent pattern that favours any of the interventions, indicating that measurement and random error can explain any perceived differences.

Poor adherence to the trial regimen was seen in over one-third of the sample. However, it seems unlikely that this explains the lack of difference between arnica and placebo since homeopathic practitioners often recommend

that a single dose of arnica before and after surgery is sufficient to hasten recovery[2]. From the study diaries it seems that more tablets were missed in the latter days of the trial when patients are likely to have fully recovered.

A final point to consider in attempting to explain the lack of difference between arnica and placebo groups is the surgical model used in this trial. There was little bruising, pain and swelling in any of the groups, so perhaps the skill of the surgeon offered little scope for arnica. However, arnica is reputed to be effective in every case of trauma, however slight[2]; some of the rigorous trials cited above have tested arnica in bigger operations without significant effects[7–13]. Conversely, it might also be argued that major tissue injury is too severe to benefit from the subtle effects of homeopathy; the present choice of surgical model represented a compromise between minor and major trauma.

In view of the ineffectiveness of homeopathic arnica observed in this and other trials, how can we account for its remarkable reputation for healing injury? The probable explanation is positive selection bias. Some patients recover very quickly from surgery. If those taking arnica attribute their good recovery to the homeopathic remedy and this apparent association is widely reported, it is easy to see how the reputation can build. Since the experiences of patients who recover well without taking arnica and those who receive no benefit from arnica are less likely to be reported, the myth becomes reinforced.

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